

Lin-Zhi International, Inc. CLIA Categorization Matrix
LZI URINALYSIS



LZI Packaged Products that have been CLIA Categorized (with LZI labeling)

Reference #	Assay Name	Hitachi 717	Beckman CX4CE	Beckman AU 400e	Beckman AU 480	Beckman AU 680
0290/0291	6-Acetylmorphine	FDA			CLIA	
	510(k) # / CR #	k101195			CR190555	
	Decision Date	7/6/2010			10/3/2019	
0040/0041	Amphetamines (1000)		FDA		CLIA	
	510(k) # / CR #		k020395		CR200038	
	Decision Date		6/4/2002		2/21/2020	
0100/0101	Amphetamines 500	510k				
	510(k) # / CR #	k102210				
	Decision Date	12/28/2010				
0140/0141	Barbiturate	FDA				
	510(k) # / CR #	k032764				
	Decision Date	11/3/2003				
0130/0131	Benzodiazepine	FDA				
	510(k) # / CR #	k032365				
	Decision Date	9/5/2003				
0270/0271	Buprenorphine	FDA			CLIA	CLIA
	510(k) # / CR #	k090844			CR170552	CR160659
	Decision Date	7/30/2009			11/24/2017	1/9/2017
0030/0031	Cocaine Metabolite (300)		FDA		CLIA	
	510(k) # / CR #		k020763		CR200253	
	Decision Date		5/10/2002		6/17/2020	
0340/0341	Cocaine Metabolite 150	FDA			CLIA	
	510(k) # / CR #	k113139			CR200253	
	Decision Date	11/22/2011			6/17/2020	
0520b/0521b	Cotinine II				FDA	
	510(k) #				k192299	
	Decision Date				11/21/2019	
	CR #				CLIA	
	Decision Date				CR190258	
0160/0161	Ecstasy (MDMA)	FDA				
	510(k) # / CR #	k033094				
	Decision Date	12/19/2003				
0220/0221	Ethyl Alcohol	FDA				
	510(k) # / CR #	k032461				
	Decision Date	10/3/2003				
0450/0451	Ethyl Glucuronide III	(Forensic Use Only)				
	Validation Date				VALIDATED	

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0310/0311	Fentanyl (Qualitative)				CLIA	FDA
	510(k) # / CR #				CR200039	k181159
	Decision Date				2/25/2020	12/3/2018
0380/0381	Hydrocodone (100)				FDA	
	510(k) # / CR #				k141055	
	Decision Date				6/13/2014	
0390/0391	Hydrocodone (300)				FDA	
	510(k) # / CR #				k141055	
	Decision Date				6/13/2014	
0630/0631	Methadone II					FDA
	510(k) #					k192433
	Decision Date					10/4/2019
	CR #					CLIA
	Decision Date					CR190554
						10/11/2019
0190b/0191b	Methadone Metabolite (EDDP) "b"				FDA	
	510(k) # / CR #				k170416	
	Decision Date				6/26/2017	
0350/0351	Methamphetamine	FDA			CLIA	
	510(k) # / CR #	k113661			CR190350	
	Decision Date	1/23/2012			7/9/2019	
0330/0331	Opiate 2000	FDA				
	510(k) # / CR #	k120761				
	Decision Date	5/8/2012				
0020b/0021b	Opiates "b"	FDA				
	510(k) # / CR #	k110298				
	Decision Date	7/15/2011				
0610/0611	Oxycodone III				FDA	
	510(k) #				k202007	
	Decision Date				9/17/2020	
	CR #				CLIA	
	Decision Date				CR200357	
					9/21/2020	
0010/0011	Phencyclidine	FDA				
	510(k) # / CR #	k020254				
	Decision Date	5/10/2002				
0120/0121	Propoxyphene	FDA				
	510(k) # / CR #	k023795				
	Decision Date	1/21/2003				

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0370/0371	Carisoprodol Metabolite (SOMA)			De Novo		
	510(k) #			DEN170010		
	Decision Date			4/20/2018		
				CLIA		
	CR #			CR170081		
	Decision Date			4/27/2018		
0400/0401	SPICE I (JWH-type)	(Forensic Use Only)				
	Validation Date				VALIDATED	
0420/0421	SPICE II (XLR-11/UR-144)	(Forensic Use Only)				
	Validation Date				VALIDATED	
0070c/0071c	THC (Cannabinoid)	FDA				
	510(k) # / CR #	k110239				
	Decision Date	6/23/2011				
0410/0411	Tramadol				FDA	
	510(k) #				k201223	
	Decision Date				6/4/2020	
					CLIA	
	CR #				CR200227	